UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,857	09/21/2005	Yoshiki Sakai	Q86423	3549

65565 7590 02/08/2008

SUGHRUE-265550
2100 PENNSYLVANIA AVE. NW
WASHINGTON, DC 20037-3213

EXAMINER	
JAVANMARD, SAHAR	
ART UNIT	**PAPER NUMBER**
1617	
MAIL DATE	**DELIVERY MODE**
02/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,857	SAKAI ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-22,24,25,27,28 and 30-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-22,24,25,27,28 and 30-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/ are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *18 February 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

This Office Action is in response to the Response to Restriction Requirement filed on November 28, 2007. Claims 3-22, 24-25, 27-28, and 30-37 are pending in this Application. Claims 34-37, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions. Claims 23, 26 and 29 have been cancelled. Claims 3-22, 24-25, 27-28, and 30-33 are examined herein as they read on the elected invention.

Election/Restriction

This Office Action is in response to Applicant's Restriction Requirement remarks filed on January 3, 2008. Claim(s) 3-22, 24-25, 27-28, and 30-37 are pending. Claims 23, 26 and 29 have been cancelled. Claim(s) 34-37are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, thereby being no allowable generic or linking claim. Applicant's election of Group I drawn to an agent comprising an effective amount of ornoprostil and an effective amount of diclofenac or a salt thereof without traverse of the restriction requirement in the reply is acknowledged. The requirement is deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 3-11, 14-22, 24-25, 27-28, 30, 32, and 33 are rejected under 35 U.S.C. 102(a) as being anticipated by Sakai et al. (CA 2438241 A1).

Sakai teaches medicinal compositions containing diclofenac and ornoprostil in a single formulation (abstract; page 5, lines 9-12), meeting the limitations of claim 3.

Further Sakai teaches that dosages of diclofenac and ornoprostil are administered orally each within a range from 10 mg to 200 mg and a range from 0.1 μg to 20 μg, respectively (page 15, lines 10-14), meeting the limitations of claims 4-6.

The reference teaches a manufacturing method of soft capsules is obtained in which ornoprostil is mixed with diclofenac. The soft capsules are obtained by making a prescription solution, which is obtained by dissolving and distributing each active constituent with a stabilizing agent (medium chain triglyceride, sugar, sugar alcohol, oligosaccharide, hydroxypropylcellulose, hydroxypropylmethylcellulose, hydroxypropyl starch, hydroxypropyl methylcellulose acetate succinate, hydroxypropylmethylcellulose phthalate, polyvinylpyrrolidone, and methacrylate copolymer, etc.), and adding a

suspending agent (mono stearic acid glyceride, hardened oil, and polysorbate 80, etc.), into soft capsules by using soft capsule cover which contains gelatin, glycerin, and sugar alcohol, etc. by the law of the art (page 12, lines 8-19), meeting the limitations of claims 7, 14, 16, 20, 24, 25, 27, 28 and 30.

The reference further teaches a manufacturing method of hard capsules which contain soft capsules containing diclofenac and solution containing ornoprostil (page 14, lines 13-23), meeting the limitations of claim 8.

Sakai teaches a stabilizing agent of ornoprostil is, among other agents, a medium chain triglyceride, most preferably tricaprylin (page 10, lines 23), meeting the limitations of claims 14, 15, and 22.

The reference teaches a manufacturing method of hard capsules which contain granules, capsules or tablets containing ornoprostil and granules, capsules or tablets containing diclofenac. The desired capsules are obtained by filling soft capsules, granules or tablets of ornoprostil and soft capsules, granules or tablets of diclofenac obtained by similar method into hard capsules (gelatin or hydroxypropylmethylcellulose) by the law of the art (page 15, lines 1-8), meeting the limitations of claim 17 and 21.

Sakai teaches a manufacturing method of tablets which ornoprostil is mixed with diclofenac (page 13-14, section 3), meeting the limitations of claims 19.

Sakai teaches soft capsule preparations wherein the number of the capsules are 1 and 2 (page 16, example 1; page 17, example 2), meeting the limitations of claims 10 and 11.

Sakai teaches a hard capsule preparation which comprises at least one small soft capsule preparation comprising ornoprostil and from 40 to 95% by weight of an oily solution base (tricaprylin), and a pharmaceutical preparation comprising diclofenac salt and from 20 to 95% by weight of an excipient (crystalline cellulose) (page 20, table of hard capsule-2 components), meeting the limitations of claims 9, 32 and 33.

As per claim 18, Examiner notes that the limitation regarding "granule particle size" is given little patentable weight since this property is inherent in the disclosed active agent. "Products of identical chemical composition can not have mutual exclusive properties." Any properties exhibited by or benefits from are not given any patentable weight over the prior art provided the composition is inherent. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the disclosed properties are necessarily present. *In re Spada*, 911 F.2d 705,709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to the applicant to show that the prior art product does not inherently possess the same properties as the instantly claimed product.

Furthermore, no patentable weight is given for the "intended use" of the pharmaceutical compositions containing ornoprostil and diclofenac as recited in claims 3-22, 24-25, 27-28, 30, and 32-37. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand

alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12, 13, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai et al. (CA 2438241 A1).

Sakai is discussed above. Sakai teaches that tablets containing diclofenac can be coated with ornoprostil (page 14, lines 3-12)

Sakai does not teach coating a soft capsule comprising diclofenac with ornoprostil. Further, the reference does not specifically teach the dimensions of the soft capsules.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed the ornoprostil coating of the tablets as taught by Sakai and used the same coating for the soft capsule. Employing pharmaceutically acceptable carriers, excipients, law of the art formulations in pharmaceutical compositions, including capsule dimensions, is generally considered prima facie obvious.

Conclusion

Claims 3-22, 24-25, 27-28, and 30-33 are not allowed.

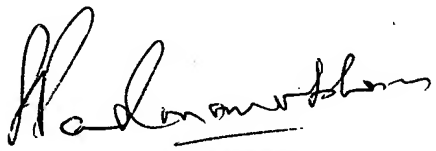
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

SJ



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER